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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,572

Applicant(s)

KLEIN ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

PD

DETAILED ACTION

1. The amendment submitted 25 February 2005 has been received. Claims 1-18 and 23-30 are pending.

Claim Rejections - 35 USC § 112

2. Claims 3-8, 10, 12, 14-18 and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague with respect to step d). It is unclear what the "eluted complex of uncomplexed first binding partner" is. It appears that the word "of" should be --or--.

Claim 4 is indefinite because it does not further limit claim 3 from which it depends.

Claim 23 is confusing because it is unclear what is being detected. The claim recites contacting a sample which is suspected of containing "an analyte of a substance of interest" with a matrix containing a first binding partner specific for *an analyte of said substance*, and a binding of the *analyte of said substance* to the first binding partner, follows by eluting any complexes and determining the identity of the substance by detecting the complexed or uncomplexed first binding partner. It is unclear what the "*analyte of said substance*" is, how it is defined and how its detection leads to the detection of the substance. For example, the "substance" is recited in claim 24 as

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nitroglycol, what is the "analyte" of nitroglycol? It is unclear what is being detected in this claim.

Likewise, the "analyte" of the various substances recited in claims 24, 25 and 26 have not been defined.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 15-18 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek et al (DE 41 21 493 A1 - English Abstract) in view of Abuknesha et al (WO 93/11430).

Scholtissek discloses a method and device in which air to be examined is passed through a filter and any narcotic contained in the air is selectively adhered or absorbed on the filter. The adhered narcotic is eluted and dissolved in a solution and an antibody to the narcotic is mixed with the sample to detect the presence and amount of the narcotic. See English abstract.

Scholtissek differs from the instant invention in failing to teach a binding partner contained in the filter.

Abuknesha, however, discloses a device and method for collecting analyte in a gaseous medium. Abuknesha teaches that a binding partner for the analyte can be covalently linked or sorbed on to a carrier mean, i.e. a nitrocellulose membrane (pages 6 and 7) and the analyte from a gaseous phase is allowed to contact the binding partner and form a complex comprising the binding partner and the analyte. Abuknesha teaches the detection of complexed or uncomplexed binding partners as a measure of the analyte. Abuknesha also teaches a separation step as well as post reaction binding modification. See pages 12-21.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method taught by Scholtissek to include a binding agent in the carrier matrix such as taught by Abuknesha because Abuknesha teaches that it is well known in the art to include a reagent for capturing the analyte on a carrier means. A skilled artisan would have had a reasonable expectation of success in including a first capture reagent in a carrier matrix and using the carrier matrix to capture analyte in a gaseous sample because both Scholtissek and Abuknesha teaches using a filter material to capture analyte in gaseous samples, and Abuknesha teaches that the incorporation of binding partner into a carrier matrix is conventional and well known as well as providing a convenient means to effectively capture minute amount of trace narcotic in the air.

5. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek et al in view of Abuknesha et al as applied to claims 1-8, 15-18 and 23-27 above, and further in view of Schlipfenbacher et al (US 5,160,486).

The references of Scholtissek and Abuknesha have been discussed above. These references differ from the instant invention in failing to teach the liquid content of the carrier matrix.

Schlipfenbacher, however, teaches a test carrier for immunoassay comprising a fleece material. Schlipfenbacher discloses a variety of material with different water uptake and output properties. See column 10.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose any of the fleece material taught by Schlipfenbacher as the carrier means in the device and method taught by Scholtissek as modified by Abuknesha because Schlipfenbacher teaches that a special importance for the function of test carriers is the retention of water under certain defined experimental conditions, therefore, depending on the requirements of an assay, a skilled artisan would have had a reasonable expectation of success in choosing an appropriate fleece material according to the guidelines set forth by Schlipfenbacher. Furthermore, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable, and absent unexpected results, it would have been obvious for one of ordinary skill to discover the

optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

6. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholtissek in view of Abuknesha and Schlipfenbacher.

Even though these references fail to specifically state the gas permeability of the carrier matrix, they do teach carrier matrix permeable to gas and liquid, therefore, a skilled artisan would have a reasonable expectation of success in choosing the appropriate carrier matrix for use in the method and device of Scholtissek as modified by Abuknesha and Schlipfenbacher because it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims are for any particular purpose or solve any stated problem and the prior art teaches that the choice of an appropriate carrier matrix is dependent on the experimental conditions which often vary according to the sample being analyzed,

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various solutions and parameters appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

Response to Arguments

7. Applicant's arguments filed 25 February 2005 have been fully considered but they are not persuasive..

Applicant argues that neither Scholtissek nor Abuknesha teach a matrix having a binding partner for the analyte in elutable form. Applicant asserts that Scholtissek teaches a device and method where the binding partner of the analyte is immobilized to the matrix and cannot be eluted therefrom. Applicant also argues that Abuknesha does not teach an elutable binding partner specific for the analyte. Applicant argues that the binding partner taught by Abuknesha does not correspond to the binding partner of the instant claims.

These arguments have been fully considered but are not persuasive. Scholtissek teaches the detection of analyte in a gaseous sample. Abuknesha teaches an embodiment where an analyte analogue is immobilized to a gas and liquid permeable carrier matrix. A labeled binder (e.g. an antibody) specific to the analyte is bound to the analyte analogue. When sample is introduced to the matrix, the labeled binder displaces from the analyte analogue and binds to the analyte in the sample. See page

11, starting at the third full paragraph through page 12, line 9. This embodiment is seen to be equivalent to "the first binding partner of the analyte in an elutable form" because it can clearly be seen that a complex comprising the labeled binder and the analyte is displaced from the carrier means as taught by Abuknesha. See page 12, lines 8-9. The fact that the labeled binder is present in the matrix through the binding of an immobilized species is irrelevant since the instant claims do not exclude such an embodiment. The limitation of "a carrier matrix containing a binding partner of the analyte in elutable form" is met because Abuknesha clearly teaches that the labeled binder is displaced from the matrix.

Applicant argues that Abuknesha does not clearly indicate what separation steps are performed and does not specifically teach an elution step.

This argument is not persuasive. Scholtissek teaches that the adhered narcotic is eluted and dissolved in a solution and an antibody to the narcotic is mixed with the sample to detect the presence and amount of the narcotic. Abuknesha teaches that a complex comprising a labeled antibody and the analyte can be displaced from a carrier means. Abuknesha also teaches post-binding modifications such as a separation between the bound and unbound labeled antibody, therefore, it would have been obvious to one of ordinary skill in the art to modify the device and method taught by Scholtissek to include a binding agent in the carrier matrix such as taught by Abuknesha because Abuknesha teaches that it is well known in the art to include a reagent for capturing the analyte on a carrier means. The inclusion of a specific binding

agent such as taught by Abuknesha would also provides the advantage of a selective and specific capture of the desired analyte. A skilled artisan would have had a reasonable expectation of success in including a first capture reagent in a carrier matrix and using the carrier matrix to capture analyte in a gaseous sample because both Scholtissek and Abuknesha teaches using a filter material to capture analyte in gaseous samples, and Abuknesha teaches that the incorporation of binding partner into a carrier matrix is conventional and well known as well as providing a convenient means to effectively capture minute amount of trace narcotic in the air.

Applicant argues that Abuknesha does not teach the detection of analyte directly from the gas phase. Instead Abuknesha teaches that a liquid sample or an aqueous spray be formed from the gaseous sample containing the analyte.

This argument is not persuasive. Scholtissek teaches the collection of analyte from a gaseous sample. Abuknesha teaches at page 2, lines 20-23, obtaining from the gaseous medium a sample containing an analyte species and applying such analyte species to the carrier means. It is noted that the instant claims do not exclude a step in which the analyte from the gaseous sample is obtained through the application of an aqueous spray, for example. The instant claims recite "contacting a gas phase with said matrix"; however, this is not interpreted as a direct contact between the gas the matrix, only that the gas sample is contacted with the matrix such that analyte present in the sample binds to the binding partner in the matrix. Abuknesha meets this limitation.

Applicant argues the Schlipfenbacher does not cure the deficiency of the Scholtissek and Abuknesha because Schlipfenbacher does not suggest an elutable binding partner for the analyte.

This argument is not persuasive. Abuknesha teaches the elutable binding partner. Schlipfenbacher is cited for their teaching of a variety of fleece material with different water uptake and output properties. Therefore, depending on the requirements of an assay, a skilled artisan would have had a reasonable expectation of success in choosing an appropriate fleece material according to the guidelines set forth by Schlipfenbacher.

Conclusion

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date


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of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
5/4/05